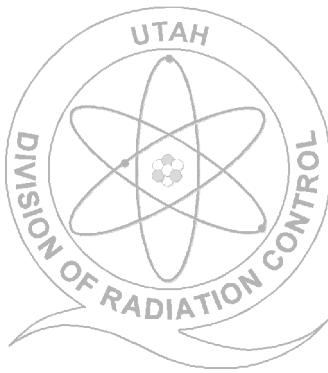


GUIDELINE FOR THE EVALUATION OF DENTAL X-RAY EQUIPMENT



State of Utah
Department of Environmental Quality
Division of Radiation Control

GUIDELINE FOR THE EVALUATION OF DENTAL INTRAORAL DIAGNOSTIC X-RAY EQUIPMENT

DRC Inspection Program Objective

The overall objective of the Division of Radiation Control (DRC) x-ray inspection program is to reduce the likelihood that individuals will be exposed to unnecessary radiation. In the case of registrants using x-ray equipment in the healing arts, patient exposure is of concern and proper equipment performance is essential. Registrants are required to demonstrate that equipment satisfies the appropriate regulatory standards for calibration and performance.

Purpose of Guideline

The intent and purpose of this document is to provide users of dental x-ray equipment guidelines for the documentation necessary to demonstrate to the DRC that x-ray equipment satisfies the regulatory standards under clinical use conditions.

Intraoral X-ray Equipment Performance and Calibration

The registrant is to document that the following requirements are met:

- 1) adequate total filtration is present.
- 2) kVp calibration is adequate for the mA station or stations (mAs stations if mA is not a technique factor that can be chosen) used clinically.
- 3) mA/mAs linearity is satisfied.
- 4) the timer, if present, is accurate for those time values most frequently used.
- 5) timer linearity is satisfied.
- 6) exposures are reproducible.
- 7) means shall be provided to limit the x-ray field.

The following examples are presented as guidance for what will be considered an adequate evaluation, with support documentation, to demonstrate compliance:

1) Adequate Filtration

Demonstration of adequate filtration shall be accomplished by showing that the half value layer (HVL) exceeds the minimum regulatory standard. For example, with equipment where the maximum kVp is 70, at a kVp value of 70, the HVL is to be equal to or greater than 1.5 mm aluminum. At a measured kVp value of 80, the HVL is to be equal to or greater than 2.3 mm aluminum. This can be demonstrated by:

- a) measuring the in air exposure when different thicknesses of aluminum intercept the x-ray beam and calculating the HVL value; or
- b) measuring the exposure at 70 kVp with and without a 1.5 mm aluminum absorber intercepting the x-ray beam and showing that the ratio of the two exposure values exceeds 0.5.
- c) measuring the exposure at 80 kVp with and without a 2.5 mm aluminum absorber intercepting the x-ray beam and showing that the ratio of the two exposure values exceeds 0.5.

(Documentation shall include a listing of the measured exposure values and associated thicknesses of aluminum.)

2) kVp Calibration

Accuracy of the kVp is to be determined under simulated clinical conditions.

Example 1: All Intraoral dental procedures are performed on a particular x-ray unit at 70 kVp and 7 mA (both techniques are fixed). In this case the kVp accuracy can only be measured at 70 kVp.

Example 2: The dental intraoral x-ray unit is operable at 60 and 70 kVp, and is used clinically at both kVp settings. The kVp is to be measured at 60 and 70 kVp.

(Documentation shall include the mA and kVp indicated as well as kVp measured.)

3) mA/mAs Linearity

The regulatory standards require mA/mAs linearity be satisfied as follows:

- a) Output linear in mA: For a given kVp, time and mA setting the difference in the mR/mAs exposure on any two adjacent mA stations or two mA stations differing by no more than a factor of two shall not differ by more than 0.10 times the sum of the two values.
- b) Output linear in mAs: For a given kVp and mAs value the difference in the mR/mAs output on any two adjacent mAs setting or at two settings differing by no more than a factor of two, shall not differ by more than 0.10 times their sum.

Example 1: Dental bitewing procedures are performed at 90 kVp using either the 10 or 15 mA stations and one of the following timer values; 10 or 12 impulses. The linearity in the 10 and 15 mA station at 90 kVp will be evaluated since both mA stations are used clinically.

Example 2: Dental bitewing procedures are performed at 70 kVp and mAs values of 3 and 45 (time is not a technique factor and there is not a mA selector but rather a continuous change in tube current with mAs value). Linearity will be determined between the mAs values used clinically.

(Documentation will indicate the technique values used clinically for which the mA/mAs linearity condition is being evaluated. Measured exposure values and the associated mR/mAs values will also be included.)

4) Timer Accuracy

For x-ray equipment with time settings, the accuracy of the timer shall be evaluated for the time settings used clinically. Preheat time may effect your determination of timer accuracy. Preheat characteristics depend on the x-ray unit manufacturer and model type as well as incoming line voltage and voltage compensation.

Example: Dental bitewings are performed at 70 kVp, 7 mA, and 22 impulses (366 msec). The timer setting is occasionally changed to 25 and 28 impulses. At a minimum, the unit will be evaluated at 22 and 25 impulses.

(Documentation shall identify the x-ray procedures for which the timer is evaluated, time settings being evaluated, and the measured time values.)

5) Timer Linearity

For systems having independent selection of exposure time settings, the average ratio of exposure to the indicated milliamperes-seconds product obtained at two consecutive time settings or at two settings not differing by more than a factor of two shall not differ by more than 0.10 times their sum.

Example: Dental bitewings are performed using 70 kVp, 7 mA, 0.32 and 0.4 second. Timer linearity will be determined between these two clinically used timer settings.

(Documentation will indicate the measured exposure values and the associated mR/mAs values.)

6) Exposure Reproducibility

Reproducible exposures are to be evaluated for technique factors used clinically. For a series of exposures, where the technique factors are held constant, the coefficient of variation (COV) for certified x-ray equipment shall be less than or equal to 0.05.

Example : Dental bitewing procedures are performed using 70 kVp; 7 mA, .32 and .4 second. As a minimum, reproducibility of exposure will be evaluated at one of the times values used clinically.

(Documentation will include the technique factors used in the evaluation, the in-air exposure values obtained, and the calculated COV when necessary.)

7) X-ray Field Collimation

Means shall be provided to limit the x-ray field to a diameter of six or seven centimeters depending upon the SSD.

Example 1: If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD, shall be contained in a circle having a diameter of no more than seven centimeters.

Example 2: If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD, shall be contained in a circle having a diameter of no more than six centimeters.

(Documentation shall indicated that the evaluation has been performed and the system meets the regulatory standards.)

DENTAL PANORAMIC X-RAY EQUIPMENT PERFORMANCE AND CALIBRATION

The registrant is to document that the following requirements are met:

- 1) adequate total filtration is present.
- 2) exposures are reproducible.

(See Adequate Filtration and Exposure Reproducibility for Intraoral X-ray Equipment as described above).

DENTAL CEPHALOMETRIC X-RAY EQUIPMENT PERFORMANCE AND CALIBRATION

The registrant is to document that the following requirements are met:

- 1) adequate total filtration is present.
- 2) kVp calibration is adequate for the mA station or stations (mAs stations if mA is not a technique factor that can be chosen) used clinically.
- 3) mA/mAs linearity is satisfied.
- 4) the timer is accurate for those time values most frequently used.

- 5) timer linearity is satisfied.
- 6) exposures are reproducible.
- 7) the x-ray field is collimated and aligns with the image receptor as follows:
 - a) the bottom edge of the x-ray field (closest to the thyroid gland) does not extend beyond two percent of the SID.

(See intraoral equipment performance and calibration above for further detail. Note: The difference in cephalometric evaluation and an intraoral evaluation is 1) the bottom edge of the x-ray field must be evaluated for collimation and can not extend more than two percent of the SID, 2) if two or more kVp settings are used clinically, a minimum of two kVp settings should be measured and 3) if two or more mA stations are used clinically, a minimum of two settings should be evaluated for accuracy and linearity).